



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,850	07/15/2003	Philip E. Thorpe	4001.003082/UTSD:0893--1	2541

52101 7590 03/02/2007
PEREGRINE PHARMACEUTICALS, INC.
5353 WEST ALABAMA
SUITE 306
HOUSTON, TX 77056

EXAMINER

YAO, LEI

ART UNIT	PAPER NUMBER
----------	--------------

1642

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/620,850

Applicant(s)

THORPE ET AL.

Examiner

Lei Yao, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/20/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/7/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1642

Response to Argument and Amendment

The Amendment filed on 11/20/06 in response to the previous Non-Final Office Action (5/16/06) is acknowledged and has been entered.

Applicants request rejoinder of all claims in the response filed 11/20/06. Applicant's request is held in abeyance for the method claims (claim 14-19) until the product claims are allowable. However, the requirement for species election is withdrawn in light of the art, thus, claims 6-8 and 10-11 reciting species of conjugated antibodies are joined to claims 1-5, 9, 12 and 13 reciting naked antibody for examination at this time.

Claims 1-19 are pending. Claims 14-19 (method of using) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group. Claims 1-13 (composition) are under consideration.

The text of those sections of Title 35, U.S.Code not included in this action can be found in the prior Office Action.

The following office action contains NEW GROUNDS of rejection.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 12/7/06 are/is considered by the examiner and initialed copies/copy of the PTO-1449 are/is enclosed.

Response to Arguments

Rejection under 35 USC § 112, first paragraph-Deposit.

Claims 1-5, 9, and 12-13 remain and 6-8 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, enablement for lacking complete evidence of the deposit of biological materials.

Applicants submitted a declaration of biological culture deposit by Philip E. Thorpe based on the Office's requirement. However, the declaration is insufficient to overcome the rejection because no signature is attached in the declaration. Therefore, the rejection is maintained until a signed declaration is submitted to the Office.

Art Unit: 1642

The following is a New Ground of rejection-based on new consideration**Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. *In re Berg*, 140 F.3d, 1428, 46 USPQ2d 1226 (Fed. Cir. 1998), *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985), *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Instant claims:

Claim 1 of instant application is drawn to a composition comprising monoclonal antibody 3G4, antigen-binding region produced by hybridoma ATCC PTA 4545, wherein the monoclonal antibody binds to the phosphatidylserine. Claims 2-5 are further drawn to claim 1, wherein the antigen-binding region is fragment of 3G4. Claim 9 is further drawn to claim 1, wherein composition comprises pharmaceutically acceptable composition. Claim 12 is drawn to 3G4 produced by hybridoma ATCC 4545. Claim 6 is drawn to the composition of claim 1, wherein the composition comprised an immunoconjugate of 3G4 antibody. Claims 7-8 are further drawn to claim 6, wherein the immunoconjugate comprises 3G4 linked to a therapeutic agent, or detectable label or diagnostic agent attached to 3G4. Claims 10-11 are further drawn to claim 1, wherein the composition comprises anti-cancer agent. Claim 13 is drawn to a kit comprising composition of claim 1 and anti-cancer agent.

1. Claims 1-6, 9, and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 36, 37, 29, 43, 44, 30, 48 and 49 of copending Application No. 10642099 ('099). Although the conflicting claims are not identical, they are not patentably distinct from each other because the immunoconjugate, composition and/or pharmaceutical composition

Art Unit: 1642

of instant claims and the claims in copending application comprise the same antibody 3G4 produced by hybridoma ATCC 4545.

Claims 1-6, 9, and 12 of instant application are set forth above.

In copending application 10642099 ('099):

Claim 1 is drawn to an immunoconjugate comprising a monoclonal antibody, or antigen-binding fragment thereof, that binds to phosphatidylserine and effectively competes with monoclonal antibody 3G4 (ATCC PTA 4545) for binding to phosphatidylserine, wherein the antibody attached to first biological agent. Claim 36, further drawn to the claim 1, claims the same monoclonal antibody 3G4 produced by the same hybridoma ATCC PTA 4545 in the immunoconjugate. Claim 37 claims the same immunoconjugate comprising 3G4 produced by hybridoma ATCC PTA 4545 or antigen-binding fragment thereof attached to a biological agent. Claim 29 is drawn to a composition comprising an immunoconjugate that comprise monoclonal antibody, or antigen-binding fragment thereof, that binds to phosphatidylserine and effectively competes with monoclonal antibody 3G4 (ATCC 4545) for binding to phosphatidylserine. Claim 43, further drawn to claim 29, claims the same monoclonal antibody 3G4 produced by the same hybridoma ATCC PTA 4545 in the composition. Claim 44 claims the same composition comprising the immunoconjugate comprising 3G4 produced by hybridoma ATCC PTA 4545 or antigen-binding fragment thereof attached to a biological agent. Claim 30 is drawn to a pharmaceutical composition comprising an immunoconjugate that comprise monoclonal antibody, or antigen-binding fragment thereof, that binds to phosphatidylserine and effectively competes with monoclonal antibody 3G4 (ATCC 4545) for binding to phosphatidylserine. Claim 48, further drawn to claim 30, claims the same monoclonal antibody 3G4 produced by the same hybridoma ATCC PTA 4545 in the composition. Claim 49 claims the same pharmaceutical composition comprising the immunoconjugate comprising 3G4 produced by hybridoma ATCC PTA 4545 or antigen-binding fragment thereof attached to a biological agent.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make an immunoconjugate in a composition of instant claims with the 3G4 antibody produced by hybridoma ATCC PTA 4545 linked to biological agent based on the teachings of the

Art Unit: 1642

immunoconjugate (claims 1, 36, 37), the composition (claims 29, 43, and 44) and pharmaceutical composition (claims 30, 48 and 49) of copending application '099, which all comprise 3G4 antibody produced by hybridoma ATCC PTA 4545. One would have been motivated with a reasonable expectation of success to make such immunoconjugate in a composition comprising immunoconjugate antibody linked to biological agent, wherein the antibody is 3G4 produced by hybridoma ATCC PTA 4545 because the immunoconjugate, the composition, and pharmaceutical composition comprising the active antibody 3G4 are taught by the claims in copending application '099.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1-5, 9, and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 105, 106, 96, 111, 112, 97, 116, 117, 98, 121 of copending Application No. 10621269 ('269). Although the conflicting claims are not identical, they are not patentably distinct from each other because the immunoconjugate, composition and/or pharmaceutical composition of instant claims and composition claimed in copending application 2'269 encompass the same antibody 3G4 produced by hybridoma ATCC 4545.

Claims of instant application are set forth above.

In copending application '10621269 ('269):

Claim 1 is drawn to a composition comprising a monoclonal antibody, antigen binding fragment thereof, competes with monoclonal 3G4, produced by hybridoma ATCC PTA 4545. Claim 105 is further drawn to claim 1, wherein the antibody is the same monoclonal antibody 3G4 produced by the same hybridoma ATCC PTA 4545. Claim 106 is drawn to a pharmaceutical composition comprising the same monoclonal antibody 3G4 produced by the same hybridoma ATCC PTA 4545. Claim 96 drawn to a pharmaceutical composition comprising a monoclonal antibody, antigen binding fragment thereof, competes with monoclonal 3G4, produced by hybridoma ATCC PTA 4545. Claim 111 is further drawn to claim 96, wherein the antibody is the same monoclonal 3G4 produced by hybridoma ATCC PTA 4545. Claim 112 claims a pharmaceutical composition comprising the same monoclonal antibody 3G4 produced

Art Unit: 1642

by the same hybridoma ATCC PTA 4545. Claim 97 drawn to a purified a monoclonal antibody, antigen binding fragment thereof, competes with monoclonal antibody 3G4 produced by hybridoma ATCC PTA 4545. Claims 116 is further drawn to claim 97, wherein the antibody is the same antibody 3G4 produced by hybridoma ATCC PTA 4545. Claim 117 claims the same monoclonal antibody 3G4 produced by hybridoma ATCC PTA 4545. Claims 98 and 121 claim the same hybridoma ATCC PTA 4545 producing the same antibody 3G4.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a composition of instant claims using the same antibody of 3G4 produced by hybridoma ATCC PTA 4545 in the composition of claims 1, 105, and 106, the antibody in pharmaceutical composition of claims 96, 111, and 112 and the purified antibody of claims 97, 116, 117 of copending application '269. One would have been motivated a reasonable expectation of success to make such a composition comprising the antibody 3G4 produced by hybridoma ATCC PTA 4545 because the composition comprising the same antibody 3G4 has been taught in the copending application '269.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-6 and 9-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27 of copending Application No. 10642116 ('116). Although the conflicting claims are not identical, they are not patentably distinct from each other because the immunoconjugate, composition and/or pharmaceutical composition of instant claims and composition claimed in copending application 2'269 encompass the antibody binding to same epitope of 3G4 produced by hybridoma ATCC 4545.

Claims of instant application are set forth above.

Claim 27 of copending application 10642116 ('116) claims a kit comprising anti-phosphatidylserine antibody and antigen-binding fragment thereof, wherein the antibody binds to substantially the same epitope as the monoclonal antibody 3G4 (ATCC PTA 4545) and a second therapeutic agent.

Art Unit: 1642

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a composition or a kit of instant claims with 3G4 antibody based on the teaching of the claim 27 that the antibody binding to the same epitope of 3G4 produced by hybridoma ATCC PTA 4545 with or without second therapeutic agent disclosed in the kit of claim 27 of copending application '116 for the same function of binding phosphatidylserine. One would have been motivated a reasonable expectation of success to make such a composition or a kit comprising the 3G4 antibody produced by hybridoma ATCC PTA 4545 because the claim 27 of copending application '116 teaches a kit comprising an antibody binding to the same epitope of the 3G4 and a second therapeutic agent. In addition because one skilled in the art knows that the epitope bound by a monoclonal antibody encompasses only a small and limited number of amino acids in the sequence and one amino acid change in the epitope could result in a lost of the binding ability of the antibody. Thus, a monoclonal antibody binding to the same epitope would be produced by the same hybridoma or a recombination technique using the same DNA encoding the same antibody. In this case, the antibody binding to the same epitope of 3G4 would be 3G4 antibody produced by hybridoma ATCC PTA 4545. Thus, instant claims are obvious over the claim 27 of copending application '116.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,
Examiner
Art Unit 1642

LY



SHANON FOLEY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600